(19) Federal Republic of Germany
GERMAN PATENT OFFICE
(12) Utility model

(11) Roll No. G 93 19 267.3
(51) Main class: A61F 2/06
(22) Date of application: 15.12.93
(47) Date of registration: 24.2.94
(43) Publication in Patent Bulletin: 7.4.94
(54) Title of the object:

Aortic endoprosthesis

(71) Patentee's name and address:

Dr Dierk Vorwerk of 52074 Aachen, DE; Prof Dr Rudolf W Gunther of 52074 Aachen, DE; Dipl.-Ing. Dr med Thomas Schmitz-Rode, of 52070 Aachen, DE

(74) Agent's name and address:

Dipl.-Ing. H Bauer, Patent Attorney, of 52080 Aachen

BEST AVAILABLE COPY

Utility Model Application

Applicants:
Priv.-Doz. Dr D Vorwerk
Neuenhofer Weg 17, 52074 Aachen;
Prof Dr R W Gunther,
Brusseler Ring 73c, 52074 Aachen;
Dr Th Schmitz-Rode,
Kupferstrasse 9, 52070 Aachen

Our ref: B/MJ(3788) Aachen, 9 December 1993

Re: "Aortic endoprosthesis"

The invention relates to an aortic endoprosthesis with a bifurcation of the kind which may be required in a portion of a blood vessel, preferably of the infrarenal abdominal aorta, to prevent an aortic aneurysm from resulting in a burst blood vessel.

Aortic aneurysms may be caused by weakness in the wall, such that an abdominal aorta expands to over 4 cm in diameter. The widening results in irregular flow in the affected vessel portion and coagulated blood may be deposited there. As the widening increases, the wall of course becomes thinner, resulting finally in a burst vessel and an acute danger of bleeding to death.

Generally known aortic endoprostheses have to be inserted into the vessel portion after it has been opened and exposed by a stomach operation. The wall

of the aneurysm is partly resected and the rest is placed on the one-piece plastic prosthesis and sewn up.

The object of the invention is to improve a bifurcated aortic endoprosthesis so that it can be inserted, tightly incorporated and fixed in the vascular system without a stomach operation.

To this end, according to the invention, the aortic endoprosthesis has the features disclosed in the operative part of claim 1.

According to the invention the aortic endoprosthesis is constructed and assembled from a number of components which can be successively inserted into the arterial system through small openings up to 5 mm in diameter in the skin, the components being fitted together in a complete prosthesis only when inside the vessel lumen. The prosthesis according to the invention can also be used when the aneurysm spreads to the pelvic arteries.

The bag, made of microporous fabric impermeable to blood, can be moved forward on a guide wire into the abdominal artery via a puncture in a pelvic artery and so placed in the aorta that the distal end or base of the bag points in the direction of blood flow. The guide wire will extend coaxially in one or both outlet openings of the bag. The blood flow inflates the bottom region of the bag sufficiently in spite of the two outlet openings. In this state

the bag is fixed by a radially expandable metal stent against the inner wall of the aorta in front of the bifurcation in the direction of blood flow. After a guide wire has been inserted through each outlet opening through the bag via the lumen of the metal stent, an additional prosthesis component in the form of a metal stent, likewise radially expandable, elastically coated over its entire length and bridging at least the distance between the base region of the bag and the arteria iliaca comunis can be inserted via each guide wire.

The two metal stents can be inserted by conventional catheter methods by probing the second outlet opening from the first outlet opening, guiding the wire and the catheter into the opposite pelvic artery, and drawing it in conventional manner out of the vessel towards the skin. The position of the bag can be subsequently adjusted by pulling the wire, guided in a curve through the outlet opening. Next, via the inserted guide wire, the outlet openings can be probed with two catheters starting from the two inguinal ligaments, which can then be coaxially replaced by two guide wires. The two fabric-coated stents can then be inserted, simultaneously if required, via the inserted guide wires.

In the expanded state the two metal stents press against the interior of a respective outlet opening and convert the bag into a leak-free aortic

endoprosthesis fixed in the aortic lumen and bifurcated.

Preferably, the metal stent fixing the bag against the interior of the aorta is fastened to the bag, and the bag projects to the required length beyond the distal end of the metal stent.

Endovascular assembly of the aortic endoprosthesis can be greatly facilitated if, according to another feature of the invention, the metal stent fixing the bag to the interior of the aorta and the two metal stents extending through the first-mentioned stent and through the outlet openings in the bag are spontaneously expandable.

According to another embodiment of the invention, the internal diameter of the outlet openings increases in the distal direction.

This construction, in each outlet opening near the inner base of the bag, results in a radially inwardly projecting opening edge against which the outside of the metal stent abuts tightly with increased specific pressure per unit area, thus increasing the protection against a leak.

According to a final feature of the invention, in the expanded state, the stents inserted through the outlet openings have an outer diameter 2 to 4 mm greater than the smallest internal diameter of the outlet openings.

By means of this construction the components can be interconnected in sufficiently stable and leak-free manner without the need for additional steps.

An exemplified embodiment of an aortic endoprosthesis according to the invention is diagrammatically shown in the drawings, in which:

Fig. 1 shows a condom-like bag in the inflated state;

Fig. 2 shows the bag in Fig. 1 with two guide wires, and

Fig. 3 shows the bag in Figs. 1 and 2, supplemented by a bifurcation made up of two metal stents.

In a partly-shown arterial system 1, an aorta 2 is damaged by a balloon-shaped aneurysm 7 between two renal arteries 3, 4 branching therefrom and a bifurcation terminating in two pelvic arteries 5, 6.

In Fig. 1 a bag 8 made of microporous fabric impermeable to blood and having two outlet openings 9, 10 at the base is first inserted into the aorta 2 in the region of the aneurysm 7. The bag 8, equipped with a spontaneously expanding metal stent 11, is pushed forward in the contracted state along a guide wire 12 through the pelvic artery 5 and so discharged into the aorta 2 that the metal stent 11 presses at least the top edge of the bag 8 tightly

against the inside of the aorta 2 above the aneurysm 7. In the base region of the bag 8 the guide wire 12, as shown in broken lines in Fig. 1, can be bent and guided outwards through the outlet opening 10 and the pelvic artery 6. Via the free ends of the guide wire 12, respective catheters (not shown) can be pushed forward into the bag 8 inflated by the blood stream. After removal of the guide wire 12, a single guide wire 13, 14 can be pushed through each catheter, thus completing the preparatory assembly shown in Fig. 2.

Via each guide wire 13, 14 an elastic-coated, likewise spontaneously expanding metal stent 15, 16 can be inserted in conventional manner. As Fig. 3 shows, a proximal end piece of each metal stent 15, 16 extends into the bag whereas a distal end piece of each metal stent 15, 16 projects relatively far into the pelvic artery 5, 6.

In the expanded state shown in Fig. 3, the metal stents 15, 16 are constricted in the interior of the outlet openings 9, 10 and thus tightly and sealingly connected to the bag 8. The bag and the metal stents 15, 16 form an aortic endoprosthesis bridging the aneurysm 7 and characterised in particular in that it can be inserted intravascularly in spite of the bifurcation.

CLAIMS

1. An aortic endoprosthesis with a bifurcation, characterised by a condom-like bag (8) made of a microporous fabric impermeable to blood, the bag being radially inflatable and having two outlet openings (9, 10) in its distal base region pointing in the direction of blood flow, wherein the bag when inflated can be fixed against the inside of the aorta (2) in front of the bifurcation in the direction of blood flow by a radially expandable metal stent (11), and wherein a guide wire (13, 14) can be inserted through the bag (8) via each outlet opening (9, 10) through the lumen of the metal stent (11), and a likewise radially expandable, elastically coated metal stent (15, 16) bridging at least the distance between the base region of the bag (8) and the distal arteria iliaca communis can be inserted via each guide wire and, in the expanded state, pressed against the inner surface of the outlet opening (9, 10) so that the resulting bifurcation as a whole can be fixed in leakage-free manner in the aortic lumen.

2. An aortic endoprosthesis according to claim 1, characterised in that the metal stent (11) fixing the bag (8) against the interior of the aorta is fastened to the bag (8), and the bag projects beyond the distal end of the metal stent (11).

3. An aortic endoprosthesis according to claim 1 or 2, characterised in that the metal stent (11)

fixing the bag (8) to the interior of the aorta (2) and the two metal stents (15, 16) extending through the first-mentioned stent and through the outlet openings (9, 10) in the bag (8) are spontaneously expandable.

4. An aortic endoprosthesis according to any of claims 1 to 3, characterised in that the internal diameter of the outlet openings (9, 10) increases in the distal direction.

5. An aortic endoprosthesis according to any of claims 1 to 4, characterised in that in the expanded state, the stents (15, 16) inserted through the outlet openings (9, 10) have an outer diameter 2 to 4 mm greater than the smallest internal diameter of the outlet openings (9, 10).

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☑ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☑ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.
As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.